

25. A process according to claim 14, wherein the temperature of the solution is at room temperature when placed into the freeze dryer.--

### **REMARKS**

#### **In the Claims**

All the claims are cancelled without prejudice or disclaimer. New claims are added directed at the process for preparing the lyophilisates of the invention. Support for the new claims can be found in the original claims and in the specification. Original claim 1 recited the temperature range of 30°C to 90°C. Support for 30°C to 95°C can be found, for example, on page 2, line 30. No new matter is added.

#### **The Rejections under 35 USC § 112, first and second paragraphs**

Applicants submit that the newly added claims render the rejections under 35 USC § 112 moot.

#### **The Rejections under 35 USC § 103**

The Office Action admits that Gericke et al. does not teach the claimed process, i.e., the heating step before lyophilization. None of the cited references teaches or suggests the additional step of heating the solution to be lyophilized just prior to freezing said solution.

An additional heating step is not merely optimizing the temperature of the process as the Office Action alleges. In a conventional freeze-drying process, the substance to be lyophilized is dissolved to form a solution by warming the solution if necessary. The solution is filtered and placed into a freeze dryer to be freeze dried. The cited prior art does not teach or suggest warming the solution after the solution is prepared (with optional warming), filtered, and placed into the freeze dryer.

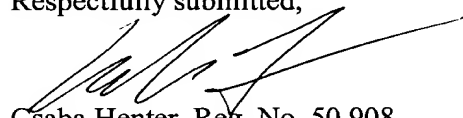
Franks teaches that the following process parameters can be controlled: shelf temperature, chamber pressure, time (cooling, annealing, primary/secondary drying cycles). See Franks, page 222, second column. Franks further teaches that the process consists of four distinct stages: 1) freezing the solution, 2) primary drying, 3) secondary drying, and 4) removing the collected ice from the condenser. See Franks, page 225, second column.

Nowhere does the prior art suggest or motivate an artisan to heat the solution after it is placed into the freeze dryer, but prior to the freezing step. Adding an entirely new untaught or unsuggested step into the process is more than mere optimization of the process. It would not have been obvious to one of skill in the art to even perform this step absent some teaching or motivation in the references to do so. Nor would it have been obvious to optimize this step, as this step is not even suggested in the references.

The rejections over the other references do not relate to the currently claimed process claims, thus the rejections over them are moot.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Csaba Henter, Reg. No. 50,908  
Anthony J. Zelano, Reg. No. 27,969  
Attorney for Applicants  
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
Arlington Courthouse Plaza 1  
2200 Clarendon Boulevard, Suite 1400  
Arlington, VA 22201  
Direct Dial: 703-812-5331  
Facsimile: 703-243-6410  
Email: henter@mwzb.com

Filed: April 29, 2002

AJZ/CH:pdrK:\Merck\2293\amendment apr 2002.doc